

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NATIONAL INSTITUTES OF
HEALTH: CONFLICTS OF
INTEREST IN EXTRAMURAL
RESEARCH**



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OBJECTIVES

1. To determine the number and nature of financial conflicts of interest reported by grantee institutions to the National Institutes of Health (NIH).
2. To determine the extent to which NIH oversees grantee institutions' financial conflicts of interest.

BACKGROUND

NIH research grants are awarded through 24 Institutes and Centers (Institutes) that have grant-making authority. Each Institute is responsible for the daily management and oversight of its grants, and each has its own grants management office that handles the grants oversight and administrative functions. Institutes follow the grants management policies outlined in the NIH Grants Policy Statement developed and implemented by NIH's Office of Extramural Research (OER). OER provides grantees with information about relevant policies and regulations through its Web site and through outreach activities such as targeted site reviews, regional seminars, and a bimonthly newsletter. OER also develops and maintains information systems related to extramural research grants administration.

Pursuant to Federal regulations, each grantee institution receiving NIH funds must have a written policy for identifying financial conflicts of interest and ensuring that conflicts will be managed, reduced, or eliminated. Grantee institutions must certify that they have written and enforced administrative processes to identify and manage, reduce, or eliminate conflicting interests. They must also certify that existing conflicts of interest (but not the nature of the interest or other details) will be reported to the Public Health Service awarding component prior to the expenditure of any funds under that award; that these conflicts have been managed, reduced, or eliminated; and that any subsequently identified conflicts will be reported and the conflicts will be managed, reduced, or eliminated, at least on an interim basis, within 60 days of identification.

We requested information regarding the receipt and oversight of grantee institutions' financial conflict-of-interest reports from OER and the 24 Institutes with grant-making authority.

FINDINGS

NIH could not provide an accurate count of the financial conflict-of-interest reports that it received from grantees during fiscal years 2004 through 2006. NIH provided us with 438 financial conflict-of-interest reports for fiscal years (FY) 2004 through 2006. However, this number does not represent the total number of conflicts of interest reported by grantee institutions because NIH's Institutes and OER were unable to provide us with all of the actual conflict-of-interest reports they received from grantee institutions.

NIH does not have a central source that can provide a total count of financial conflict-of-interest reports because OER's database of financial conflict-of-interest reports is incomplete. Although the Institutes are asked to send all conflict-of-interest reports to OER, we found that OER and the Institutes did not send us the same reports for the 3-year period.

NIH is not aware of the types of financial conflicts of interest that exist within grantee institutions because details are not required to be reported and most conflict-of-interest reports do not state the nature of the conflict. Although Federal regulations require grantee institutions to report financial conflicts of interest, the regulations do not explicitly require the nature of the conflict or other details to be reported. At least 89 percent of financial conflict-of-interest reports did not state the nature of the conflicts or how they would be managed. Because these reports contain minimal detail, grants officials have little information on which to follow up.

We determined that 30 of the 438 reports we reviewed included detailed financial conflict-of-interest descriptions. These reports described cases, for example, in which investigators have intellectual property associated with the grant research or financial interests in companies that are subcontractors on the research grants. Fifteen reports provided a detailed description of how conflicts would be managed, reduced, or eliminated. These methods included disclosing the financial conflicts of interest in presentations and publications related to the research and appointing independent faculty members to provide oversight of the grant research or to review research reports.

The information we reviewed in the 45 reports that did contain detailed information regarding the nature and management of conflicts could assist NIH officials in making a determination as to whether followup with the grantee institutions is necessary.

Many Institutes' primary method of oversight is reliance on grantee institutions' assurances that financial conflict-of-interest regulations are followed. According to the NIH Grants Policy Statement, the grantee's roles and responsibilities have assumed greater importance as NIH relegates greater decisionmaking authority to grantees. Many Institutes rely on the good faith of the grantee institutions to ensure compliance with Federal financial conflict-of-interest regulations, rather than directly overseeing or reviewing grantee institutions' management of financial conflicts of interest.

We found that the majority of the Institutes do not have any proactive methods for ensuring that grantees have financial conflict-of-interest policies. Several Institutes stated that they rely solely on information published by OER to ensure that grantees have conflict-of-interest policies in place. OER provides grantees with information about the relevant policies and regulations through its Web site. OER also conducts outreach activities, such as targeted site reviews, regional seminars, and a bimonthly newsletter to grantee institutions.

Institutes infrequently and inconsistently follow up on reported financial conflicts of interest. Our review found very few cases in which Institutes followed up with grantee institutions regarding the nature of a financial conflict of interest and/or the management plan for a financial conflict of interest.

RECOMMENDATIONS

NIH provides billions of dollars to institutions in the form of research grants. It is imperative that the funds provided to grantee institutions be used appropriately and that the research conducted using these funds not be biased because of any conflicting financial interests of investigators. Although the responsibility of complying with Federal financial conflict-of-interest regulations ultimately falls to the grantee institution, NIH, as an oversight body, should take a more active role in overseeing financial conflicts of interest among grantee institutions.

We recommend that NIH:

Increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations.

Require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated.

Require Institutes to forward to OER all financial conflict-of-interest reports that they receive from grantee institutions and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH stated that all of our findings were correct and concurred with two of our three recommendations. NIH did not concur with our recommendation to require grantee institutions to provide details regarding the nature of financial conflicts of interest and the way in which they are managed, reduced, or eliminated. NIH believes that although it is vital to maintain objectivity in research, responsibilities for identifying and managing financial conflicts of interest must remain with grantee institutions. Furthermore, NIH stated that its collection of specific details of the nature and management of financial conflicts of interest would effectively transfer the responsibility for managing financial conflicts of interest from the grantee institutions to the Federal Government.

The Office of Inspector General (OIG) continues to recommend that NIH should collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions. Collection of this information can be accomplished without interfering with grantee institutions' legal responsibility for managing financial conflicts of interest.

We continue to recommend that NIH work with the Secretary of the Department of Health and Human Services to amend the current regulation and that NIH use its authority pursuant to 42 CFR § 50.604(g)(3) to request details regarding the nature and management of financial conflicts of interest at grantee institutions.

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OBJECTIVES

1. To determine the number and nature of financial conflicts of interest reported by grantee institutions to the National Institutes of Health (NIH).
2. To determine the extent to which NIH oversees grantee institutions' financial conflicts of interest.

BACKGROUND

Each grantee institution receiving NIH funds must have a written policy for identifying financial conflicts of interest and ensuring that conflicts will be managed, reduced, or eliminated. Because outside activities may create actual or perceived conflicts of interest, it is essential that conflict-of-interest issues be addressed not only among NIH intramural researchers but also among extramural researchers receiving NIH grants. With 80 percent of NIH funding allocated for extramural research grants, it is critical that any existing or potential financial conflicts of interest be identified, disclosed, eliminated, reduced, and/or managed by grantee institutions.

National Institutes of Health Grants Administration and Oversight

NIH, located within the Department of Health and Human Services (HHS), is the primary Federal agency responsible for conducting and supporting medical research. Organized into 27 Institutes and Centers (Institutes), NIH receives billions of dollars annually to support its mission. In fiscal year (FY) 2007, the total NIH appropriation was over \$29.2 billion, 80 percent of which was distributed through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions across the country and around the world.¹

Twenty-four of the twenty-seven Institutes have grant-making authority. Each of these 24 Institutes is responsible for managing and overseeing its grants, and each has its own grants management staff that handle these functions. Grants management specialists within each Institute are responsible for the day-to-day management of a portfolio of grants. The chief grants management officer (grants officer)

¹ NIH budget information. Available online at www.nih.gov/about/budget.htm. Accessed April 27, 2007.

of each Institute is the NIH official responsible for the business management and other nonprogrammatic aspects of the award.

Institutes follow the grants management policies outlined in the NIH Grants Policy Statement developed and implemented by NIH's Office of Extramural Research (OER). OER also develops and maintains information systems related to extramural research grants administration.

Financial Conflicts of Interest

Federal regulations at 42 CFR Part 50, Subpart F, establish standards to ensure that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants will not be biased by any conflicting financial interest of an investigator. The regulations at 42 CFR § 50.605(a) provide that a conflict of interest exists when the designated official at the grantee institution “reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.” Pursuant to 42 CFR § 50.603, a significant financial interest is defined as anything of monetary value, including, but not limited to, salaries or other payments, equity interests, and intellectual property rights. The regulation excludes from this definition salaries or other payments from the investigator’s institution, income from public or nonprofit entities for selected services, salaries or other payments for services not expected to exceed \$10,000 in a 12-month period from other sources, and equity interests not exceeding \$10,000 in fair market value and not representing more than 5-percent ownership interest in any single entity.

Responsibility of Grantee Institutions

According to the NIH Grants Policy Statement, grantee institutions must have written standards of conduct that establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by financial gain for themselves or for others with whom they have close ties.

Pursuant to 42 CFR Part 50, Subpart F, each grantee institution receiving NIH funds must have a written policy for identifying financial conflicts of interest and ensuring that conflicts will be managed,

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reduced, or eliminated.² These guidelines must also indicate how outside activities, relationships, and financial interests are reviewed by responsible and objective institution officials. Pursuant to 42 CFR § 50.604, each institution must:

- (a) Maintain an appropriate written, enforced policy on conflict of interest . . . and inform each investigator of that policy, the investigator's reporting responsibilities, and of these regulations. If the institution carries out PHS-funded research through subgrantees, contractors, or collaborators, the institution must take reasonable steps to ensure that investigators working for such entities comply with this subpart. . . .
- (b) Designate an institutional official(s) to solicit and review financial disclosure statements from each investigator who is planning to participate in PHS-funded research.
- (c) (1) Require that by the time an application is submitted to PHS, each investigator . . . planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of . . . known significant financial interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research . . . and (ii) in entities whose financial interest would reasonably appear to be affected by the research. (2) All financial disclosures must be updated during the period of award, either on an annual basis or as new reportable significant financial interests are obtained.
- (d) Provide guidelines . . . for the designated official(s) to identify conflicting interests and . . . ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for at least 3 years from the date of submission of the final expenditures report. . . .
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

² Small Business Innovation Research Program and Small Business Technology Transfer Program Phase I awardees are not subject to these Federal conflict-of-interest regulations.

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- (g) Certify . . . that: (1) there is in effect . . . a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests . . . (2) prior to the institution's expenditure of any funds . . . the institution will report to the PHS awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated . . . and, for any interest that the institution identifies as conflicting subsequent to the . . . initial report . . . the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within 60 days of that identification; (3) the institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

The NIH Grants Policy Statement and the NIH grant application explain the financial disclosure responsibilities of grantees.³ By signing a grant application, the designated representative of the grantee institution is certifying that the applicant organization will comply with all applicable assurances and certifications referenced in the application, including those related to financial conflicts of interest. Grantees can find more information about their responsibilities regarding conflicts of interest on the OER Web site, which contains multiple links to additional conflict of interest resources.⁴ Information on OER's Web site includes the NIH Guide for Grants and Contracts; NIH Regional Seminars, which provide education and training on regulations and policies; and the NIH Extramural Nexus, a bimonthly newsletter from OER that provides updates on NIH policies and activities. OER also conducts presentations regarding financial conflicts of interest at professional meetings.

³ NIH Grants Policy Statement. Available online at http://grants.nih.gov/grants/policy/nihgps_2003/index.htm. NIH grant application. Available online at <http://grants.nih.gov/grants/funding/phs398/PolAssurDef.pdf>. Both accessed August 22, 2007.

⁴ Available online at <http://grants1.nih.gov/grants/policy/coi/index.htm>. Accessed May 3, 2007.

National Institutes of Health Oversight of Financial Conflicts of Interest

Although OER and Institutes share responsibility for outreach to and education of grantees with regard to financial conflicts of interest, each Institute must directly oversee its grantees in this regard. Grantees must inform their respective funding Institute's grants officer of any financial conflicts of interest before spending any NIH funds under a new grant. Conflicts identified during the grant period must be reported to the grants officer within 60 days of identifying them. These reports must indicate whether the financial conflict of interest has been managed, reduced, or eliminated. Institutes are asked, but not required, to forward reports of grantee financial conflict of interest to OER. OER developed an internal database in 2004 to capture the financial conflict-of-interest reports forwarded by the Institutes to OER; the database contains data from FY 2000 to the present.

Institute procedures for reviewing financial conflict-of-interest reports are based on guidance posted on the internal NIH Grants Management Infonet "How-To" Web site. This guidance states that the Institutes should share reports with the appropriate Institute personnel; send a letter acknowledging receipt of the reported financial conflict of interest to the grantee; send a copy of the report to the Director of the Division of Grants Policy and Oversight, Office of Policy for Extramural Research Administrations within OER and ensure that all correspondence relating to the conflict is maintained in the official file; and request additional information from the grantee and take corrective action, if necessary.

National Institutes of Health Targeted Site Reviews

In FY 2006, the Office of Policy for Extramural Research Administration began conducting targeted site reviews of grantee institutions. The targeted site review program is part of NIH's oversight responsibilities and was developed to determine whether: (1) grantee institutions are fully and correctly implementing the financial conflict-of-interest regulations at 42 CFR Part 50, Subpart F; and (2) reporting requirements are being met. NIH conducted 18 targeted site reviews in FY 2006. The 18 grantee institutions reviewed represented approximately \$4 billion in research grant awards for FY 2005.⁵ NIH reported that the \$4 billion represented

⁵ "Observations from NIH's FY 2006 Targeted Site Reviews on Financial Conflict of Interest." Available online at <http://grants1.nih.gov/grants/policy/coi/index.htm>. Accessed June 8, 2007.

approximately 25 percent of total research grant awards for FY 2005. NIH found no instances of intentional noncompliance by grantee institutions but found that more emphasis is needed on the appropriate definition of “investigator” as listed at 42 CFR § 50.603. NIH observed that grantee institutions have the most difficulty identifying and reporting financial conflicts that arise after the start of the research project and obtaining disclosures from investigators who join the project after its inception.⁶ Other compliance issues included (1) not having provisions in place to ensure that identified conflicts are reported to NIH by subgrantees through the prime grantee, (2) not having a consistent reporting process in place, (3) submitting grant applications prior to collecting significant financial interests information from investigators, and (4) expending grant funds prior to reporting identified financial conflicts of interest to NIH.⁷

METHODOLOGY

Scope

This study is limited to NIH’s oversight of financial conflicts of interest among grantee institutions. Although NIH also allocates funds to contractors, we focused only on grantees because the majority of NIH funding is allocated for research grants. In addition, NIH contractors are required to adhere to a separate set of Federal regulations governing conflicts of interest.

Data Sources and Data Collection

We collected information from the 24 grant-making Institutes at NIH and from OER. We requested the following information:

- (1) Copies of all financial conflict-of-interest reports as well as documentation related to these reports that the 24 grant-making Institutes received from grantee institutions during FYs 2004 through 2006.
- (2) Copies of all financial conflict-of-interest reports and associated documentation that OER received from Institutes during FYs 2004 through 2006.

⁶ Ibid.

⁷ Ibid.

(3) An electronic copy of the OER database that houses the financial conflict-of-interest reports forwarded by the Institutes to OER.

We also sent surveys to the Director of the Division of Grants Compliance and Oversight and the grants officers at each of the 24 grant-making Institutes. The Director and all 24 grants officers responded to our survey. Our questions covered topics such as how these offices ensure that financial conflicts of interest are reported to them; what policies and procedures for overseeing grantee conflicts of interest exist; and whether there are procedures in place to ensure that reported financial conflicts of interest have been managed, reduced, or eliminated.

Data Analysis

Some financial conflict-of-interest reports mentioned conflicts related to more than one grant. In these cases, we considered the conflicts mentioned for each grant to be a separate report.

We compared the records in OER's database to the paper copies of financial conflict-of-interest reports we received from OER to determine whether any paper reports were not entered into the database and whether there were entries in the database for which we did not receive corresponding paper reports. We then compared both OER's paper reports and electronic entries with the paper reports we received from the Institutes to determine what reports OER and Institutes had in common. Combining all paper reports gave us a total of 438 unique financial conflict-of-interest reports for our review and analysis.⁸ OER's database contained 30 entries for which we did not receive corresponding paper reports from either OER or the Institutes.

From the survey data, we determined the frequency of responses to closed-ended survey questions and reviewed and categorized responses to open-ended survey questions.

Limitations

For our analysis, we used the 438 financial conflict-of-interest reports that were received in paper form. The 30 electronic entries in OER's database for which there were no corresponding paper reports were eliminated from our analysis because we did not have the source documentation to verify them.

⁸ OER and Institutes submitted some financial conflict-of-interest reports that were outside our timeframe and were therefore not included in our analysis.

I N T R O D U C T I O N

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

NIH could not provide an accurate count of the financial conflict-of-interest reports that it received from grantees during fiscal years 2004 through 2006

NIH provided us with 438 financial conflict-of-interest reports for FYs 2004 through 2006: 73 for FY 2004, 139 for FY 2005, and 226 for FY 2006.

However, these numbers may not truly represent the total number of conflicts of interest reported by grantee institutions. NIH's Institutes and OER were unable to provide us with paper copies of all of the actual conflict-of-interest reports received from grantee institutions. Some of the Institutes were also unable to provide an accurate count or even an estimate of the reports that they received during the 3-year period.

According to OER, the Institutes are the official receipt point for financial conflict-of-interest reports from grantee institutions. The Institute is responsible for reviewing reports, determining whether further specific information is needed, and maintaining documentation. OER provided the following explanation for why Institutes were unable to provide all of the conflict-of-interest reports requested:

. . . the majority of [Institutes] maintain these reports with individual grant files by grant number. Unfortunately, because NIH has approximately 40,000–50,000 active grant awards at any given time, and each grant file contains thousands of pages of documents, finding every conflict of interest notification would require searching manually each individual grant file.⁹

NIH does not have a central source that could provide a total count of financial conflict-of-interest reports because the Office of Extramural Research's database of financial conflict-of-interest reports is incomplete

OER's database is the only centralized database in NIH that contains conflict-of-interest reports from across the Institutes. OER asks, but does not require, Institutes to forward to it the financial conflict-of-interest reports that they receive. Because the Institutes are not required to provide OER with conflict-of-interest reports, OER maintains that its database is not the official repository for all financial conflict-of-interest reports and that Institutes are responsible for maintaining documentation. We found that OER's database of financial conflict-of-interest reports was incomplete. We found that 27 conflict-of-interest reports among the

⁹ E-mail correspondence, dated March 21, 2007, from the Director of the Division of Grants Compliance and Oversight regarding the Office of Inspector General's request for all conflict-of-interest reports.

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276 provided to us by OER were not included in its database. Although all 24 Institutes responded to our survey that they forward the reports to OER, we received an additional 36 financial conflict-of-interest reports from the Institutes that were not provided to us by OER. Table 1 below shows the number of reports received from the Institutes and OER.

Table 1. Number of Financial Conflict-of-Interest Reports Provided by NIH for FYs 2004 Through 2006

Source of Financial Conflict-of-Interest Reports	Number of Reports
Provided by Institutes and OER	126
Provided by Institutes only	36
Provided by OER only	276
Total	438

Sources: NIH, 13 Institutes, and OER.

Nearly half of the Institutes were unable to provide any financial disclosure reports for fiscal years 2004 through 2006

Thirteen of the twenty-four Institutes provided us with 162 financial conflict-of-interest reports for FYs 2004 through 2006. Eleven Institutes did not provide any reports for the 3-year period.¹⁰ The 162 reports provided by the 13 Institutes may not represent all of the reports they received from grantee institutions. According to NIH, some of the Institutes may have provided only those reports that were readily accessible.¹¹

Besides requesting the actual conflict-of-interest reports, we also asked the Institutes to provide us with the number of reports that they had received for FYs 2004 through 2006. For 2006, 11 Institutes were able to provide us with the number of reports, 10 provided estimates, and 3 could provide neither. For FYs 2004 and 2005, four Institutes were

¹⁰ One of the eleven Institutes sent conflict-of-interest reports but not for the FYs 2004–2006 period.

¹¹ E-mail correspondence, dated March 21, 2007, from the Director of the Division of Grants Compliance and Oversight regarding the Office of Inspector General’s request for all conflict-of-interest reports.

unable to provide us with any information. Therefore, we cannot determine an actual or estimated number of reports that the Institutes received from grantee institutions during these years.

Conflict-of-interest reporting information is not readily available even from Institutes that have tracking systems

Thirteen of the twenty-four Institutes indicated that they have systems for tracking the financial conflict-of-interest reports that they receive from grantees. Five of these Institutes’ systems were developed sometime in FY 2007. Of the 11 Institutes that were not able to provide us with conflict-of-interest reports for FYs 2004 through 2006, five had tracking systems and three had systems that captured financial conflict-of-interest reports for all 3 years.

To retrieve information or to obtain a count of past financial conflict-of-interest reports, 11 Institutes—including 3 that indicated they had tracking systems—reported that they would have to search through individual paper or electronic grant files. Five Institutes indicated that they would retrieve this information from OER.

NIH is not aware of the types of financial conflicts of interest that exist within grantee institutions because details are not required to be reported and most conflict-of-interest reports do not state the nature of the conflict

Although Federal regulations require grantee institutions to report financial conflicts of interest, the regulations do not require them to report the nature or other details of the financial conflict of interest.

Because these reports contain minimal detail, grants officials do not know what type of conflicts exist and have little information on which to follow up.

The majority of reports did not list which individuals associated with the grants had the reported conflicts of interest. Of the 438 financial conflict-of-interest reports we received, 99 stated that the primary investigators had conflicts and 51 stated that others had conflicts.¹² From the information presented in the remaining 288 financial conflict-of-interest reports, we could not determine who had conflicts.

¹² The primary investigator is the individual, designated by the grantee, responsible for the scientific or technical aspects of the grant and for day-to-day management of the project or program.

F I N D I N G S

Although 93 percent of reports (408) did not detail the nature of the financial conflicts of interest, we reviewed 30 reports that included detailed descriptions. Some of the financial conflicts of interest that were detailed include:

- investigators who invented technology or have intellectual property associated with the grant research,
- investigators who have relationships with or financial interests in companies that are subcontractors on the grants,
- investigators whose spouses are subcontractors of the grant, and
- a grantee institution holding patents on technology used in the grant research and exclusively licensing the intellectual property to a company whose investors/owners are investigators on the grant.

Eighty-nine percent of reports (388) did not explain how conflicts are managed but provided general statements saying that the financial conflict of interest would be managed, reduced, or eliminated. The remaining 50 reports provided a description of how conflicts would be managed, reduced, or eliminated. Two-thirds of these reports stated that the conflicts would be managed through a process of disclosure but did not explain how the conflicts would be disclosed. Fifteen reports provided more detailed descriptions of how conflicts would be managed, reduced, or eliminated. These methods included disclosing the financial conflicts of interest in presentations and publications related to the research, appointing independent faculty members to provide oversight of the grant research or to review research reports, recusing investigators from the grants, and terminating relationships with companies.

The type of information we reviewed in the 30 reports that detailed the nature of conflicts and the 15 reports that detailed the management of conflicts could assist NIH officials in determining whether followup with the grantee institution is necessary. However, we found five cases in which a grantee institution resubmitted reports because NIH felt that the information originally provided was too specific or detailed. These five letters from the grantee institution stated that an assistant grants compliance officer at NIH advised a grantee that the previously submitted conflict-of-interest report included too much information.

To address the NIH officer’s concerns, the grantee institution submitted abbreviated versions of the reports.

Many NIH Institutes’ primary method of oversight is reliance on grantee institutions’ assurances that financial conflict-of-interest regulations are followed

According to the NIH Grants Policy Statement, the grantee’s roles and

responsibilities have assumed greater importance as NIH relegates greater decisionmaking authority to grantees. While each Institute is responsible for the overall management of the grants it funds, the responsibility for promoting objectivity in research lies with the grantee institution. The designated representative of the grantee institution is responsible for ensuring that the grantee organization complies with applicable Federal laws and regulations. Many Institutes rely on the good faith of the grantee institution to ensure compliance with Federal financial conflict-of-interest regulations, rather than directly overseeing or reviewing grantee institutions’ management of financial conflicts of interest.

The majority of the Institutes do not have any proactive methods to ensure that grantees have financial conflict-of-interest policies

Grantee institutions are required to certify in all NIH grant applications that they are in compliance with 42 CFR Part 50 Subpart F and, thus, have a financial conflict-of-interest policy in place. Ten Institutes indicated that the only method they use to ensure that grantees have these policies is the grantees’ self-certification of compliance on the initial grant applications. Five Institutes stated that they rely solely on information published by NIH and/or OER to ensure that grantees have financial conflict-of-interest policies in place. OER provides Institutes and grantees with information about the relevant policies and regulations through its Web site. OER also conducts outreach activities, such as targeted site reviews, regional seminars, and a bimonthly newsletter to grantee institutions. Two Institutes reported that they do nothing to ensure that grantees have financial conflict-of-interest policies in place.

Some Institutes use some type of outreach method to ensure that grantee institutions have conflict-of-interest-policies. Three Institutes use site visits and training seminars to ensure that grantee institutions have policies in place. One Institute reported that it follows up with grantees if it has any concerns. Three other Institutes reported that they use more than one of the methods described above.

Many Institutes rely solely on grantees' assurances that they are appropriately reporting and managing, reducing, or eliminating financial conflicts of interest

Nine Institutes indicated that they rely solely on the grantees to ensure reporting of financial conflicts of interest. Another four Institutes rely on the grantee institutions' self-certification of compliance on the grant applications. An additional four rely on the grant applications and/or the information published by NIH (including OER) to ensure that grantees are reporting conflicts.

Five Institutes reported using a number of methods, including outreach, training, and site visit activities, to ensure that grantees are reporting conflicts. One Institute follows up with grantees that it believes may have reporting problems. For the remaining Institute, we could not determine from its response how it ensures that grantees are reporting conflicts.

When asked what procedures they have for ensuring that financial conflicts of interest are being managed, reduced, or eliminated, 17 Institutes answered that they rely on grantees to do this. Four Institutes stated they do follow up or remind grantee institutions in acknowledgment letters about this requirement. Two rely on published NIH policies. One Institute uses a checklist when reviewing grant renewal applications to ensure that grantee institutions have procedures in place.

Institutes infrequently and inconsistently follow up on reported financial conflicts of interest

Although OER has followed up with grantee institutions during the small number of targeted site reviews it has performed (18 in FY 2006), in our review of the documentation, we observed very few instances in which Institutes followed up with grantee institutions regarding the nature or management of financial conflicts of interest. Instead, we found internal memorandums from one Institute that stated, “. . . if you have any concern that this [conflict] could harm the project, we can ask for additional information, however, this would only be done in rare/exceptional situations. . . .” An internal memorandum from another Institute stated, “We should not follow up for additional details about the nature of the conflict or how it was managed unless there is sufficient programmatic concern to do so.”

Our survey results confirm that some Institutes do not follow up on reported financial conflicts of interest. Eight Institutes stated that they

F I N D I N G S

never needed to follow up with grantee institutions regarding reported financial conflicts of interest. In addition, Institutes varied on what types of information they would request when following up with grantee institutions. Seven Institutes stated that they would request additional information from grantee institutions such as investigators' names, grant numbers, and financial conflict-of-interest policies. Five Institutes indicated that if followup was needed, they would ask for additional information regarding the nature of the financial conflict of interest and/or how the financial conflict of interest would be managed. Two Institutes indicated that they would request a combination of information described above. Another two Institutes did not respond to our question about followup with grantees.

RECOMMENDATIONS

NIH provides billions of dollars to institutions in the form of research grants. It is imperative that the funds provided to grantee institutions be used appropriately and that the research conducted using these funds not be biased because of any conflicting financial interests of investigators. The responsibility of complying with Federal financial conflict-of-interest regulations ultimately falls to the grantee institutions. However, as an oversight body, NIH should take a more active role in overseeing financial conflicts of interest among grantee institutions.

We recommend that NIH:

Increase Oversight of Grantee Institutions To Ensure Their Compliance With Federal Financial Conflict-of-Interest Regulations

OER and each of the grant-making Institutes should expand oversight activities to ensure that grantee institutions have financial conflict-of-interest policies and procedures that comply with Federal regulations. Options to implement this recommendation could include increasing site visits by OER and Institutes' collecting and reviewing grantee institutions' financial conflict-of-interest policies.

Require Grantee Institutions To Provide Details Regarding the Nature of Financial Conflicts of Interest and How They Are Managed, Reduced, or Eliminated

It is difficult to determine whether followup with grantee institutions is warranted if the details regarding the nature and management of financial conflicts of interest are not collected. Although the current regulations authorize NIH to seek additional information regarding any conflicting interest and how the interest was managed, grantees are initially required to report so little information that NIH would rarely have reason to even know that it should request follow-up information. Collecting basic details regarding the nature of financial conflicts of interest and how they are managed might enable NIH to question whether certain conflicts could affect the grant research being conducted. Collecting this information might also enable NIH to determine whether grantee institutions are appropriately managing specific types of financial conflicts of interest.

We recommend that 45 CFR § 50.604(g)(2) be amended to require grantee institutions to report certain details to the appropriate HHS public health research funding agency—in this case NIH—about any conflicting financial interest and how it was managed, reduced, or eliminated.

Enough details should be provided so that NIH can identify concerns and adequately monitor whether grantees are complying with the regulatory requirements to identify and manage conflicts. We recognize that this regulation is applicable to all Public Health Service research grants or cooperative agreements. Because NIH is responsible for the largest share of public health research funding, we recommend that NIH work with the Secretary's Office to amend the current regulation. In the meantime, we recommend that, after a grantee submits a report identifying the existence of a conflict, NIH use the current regulatory authority at 42 CFR § 50.604(g)(3) to request details about the particular financial conflict of interest and how it was managed, reduced, or eliminated.

Require Institutes To Forward to OER All Financial Conflict-of-Interest Reports That They Receive From Grantee Institutions and Ensure That OER's Conflict-of-Interest Database Contains Information on All Conflict-of-Interest Reports Provided by Grantee Institutions

Although OER asks Institutes to forward financial conflict-of-interest reports to OER, Institutes are not required to do so. A central repository for financial conflict-of-interest reports would enable NIH to have a more accurate picture of the number and nature of financial conflicts of interest reported to NIH. The absence of financial conflict-of-interest reports from grantee institutions does not necessarily indicate a problem. However, with a complete and comprehensive OER conflict-of-interest database, NIH can look at reporting and management trends and thus focus training and outreach efforts on grantee institutions where it sees potential issues or problems. Therefore, Institutes should be required to send all conflict-of-interest reports to OER for inclusion in its database.

NIH staff informed us that OER had recently developed a Web-based financial conflict of interest tracking and monitoring system for internal NIH use. Institute grants management and program staff will be able to enter their own records and view financial conflict-of-interest reports across NIH. The database will remind grants management personnel to send an acknowledgment to the institution and a copy of the report to OER. The database is in the testing phase and NIH expects to make its use mandatory in 2008.

We recommend that this new system capture the following information about each grant listed on a conflict-of-interest report: the grant number; the name of investigator or other individual or entity with the financial conflict of interest; a description of the nature of the conflict; and a description of how the conflict is managed, reduced, or eliminated.

R E C O M M E N D A T I O N S

In the future, NIH also plans to permit grantee institutions to electronically submit financial conflict-of-interest reports through eRA Commons, which is NIH's Web-based system that grantees use to conduct their extramural research administration business electronically.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH stated that all of our findings were correct and concurred with two of our three recommendations. NIH did not concur with our recommendation to require grantee institutions to provide details regarding the nature of financial conflicts of interest and the way in which they are managed, reduced, or eliminated. NIH believes that although it is vital to maintain objectivity in research, responsibilities for identifying and managing financial conflicts of interest must remain with grantee institutions. NIH also points to 42 CFR Part 50, Subpart F, which assigns responsibility for identifying and managing financial conflicts of interest to grantee institutions rather than to the Federal Government. Furthermore, NIH stated that its collection of specific details of the nature and management of financial conflicts of interest would effectively transfer the responsibility for managing financial conflicts of interest from the grantee institutions to the Federal Government. The full text of NIH's comments is presented in the Appendix.

The Office of Inspector General (OIG) continues to recommend that NIH should collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions. Collection of this information can be accomplished without interfering with grantee institutions' legal responsibility for managing financial conflicts of interest.

We continue to recommend that NIH work with the Secretary of the Department of Health and Human Services to amend the current regulation and that NIH use its authority pursuant to 42 CFR § 50.604(g)(3) to request details regarding the nature and management of financial conflicts of interest at grantee institutions.

▶ A P P E N D I X

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
<http://www.nih.gov>

DEC 10 2007

TO: Daniel R. Levinson
Inspector General, HHS

FROM: Director, NIH

SUBJECT: Office of Inspector General Draft Report, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460

We appreciate the opportunity to review and comment on the draft OIG report entitled, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460. Enclosed are our comments.

Should you or your staff have any questions, please call Ms. Diane Dean, in the NIH Office of Extramural Research, at 301-435-0930.

Again, thank you for the opportunity to comment.

Elias A. Zerhouni, M.D.

Attachment

Office of Inspector General Draft Report
National Institutes of Health: Conflicts of Interest in Extramural Research,
OEI-03-06-00460

NIH Response to OIG Findings and Recommendations

OIG Recommendations:

- 1. Increase oversight of grantee institutions to ensure their compliance with Federal financial conflicts of interest regulations.**

NIH concurs with this recommendation. NIH has been leading Federal conflict of interest (FCOI) oversight activities for many years and will continue to make this a priority.

Current and past activities include:

- NIH Pilot Compliance Program on FCOI (2007);
- Web-based reporting and tracking tool for NIH staff (2007);
- Education and outreach programs (e.g. NIH Regional Seminars; presentations at professional organizations and meetings) (ongoing since 2001);
- NIH Targeted Site Reviews (2006);
- Articles (Nexus) (2006);
- NIH Proactive Compliance Site Visits (2004);
- FCOI mailbox (2004);
- NIH Guide Notices (2007, 2004, 2003);
- NIH Review of COI Policies of Grantee Institutions (2002);
- Web postings and resource documents (<http://grants.nih.gov/grants/policy/coi/index.htm>).

Further enhancements include:

- Development of an eRA Commons FCOI module/reporting tool for grantee institutions to report FCOIs;
- Updated and expanded FAQs on FCOI;
- Development of an on-line tutorial.

- 2. Require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated.**

Amend 45 CFR § 50.604(g)(2) [sic] to require grantee institutions to report certain details to the appropriate HHS public health research funding agency about any conflicting financial interest and how it was managed, reduced, or eliminated.

NIH does not concur with these recommendations. We believe that it is vital to maintain objectivity in research; however, responsibilities for identifying and managing FCOIs must remain with grantee institutions. Routine collection of the details of the nature and management of FCOI would effectively, if not legally, transfer the locus of

responsibility for managing FCOIs from the grantee institution to the Federal Government. Title 42 CFR Part 50 Subpart F assigns responsibility for identifying and managing FCOI to grantee institutions rather than to the Federal Government. The rationale for that provision is sound. Authority needs to be exercised with full knowledge of the implications of an action as this is critical to ensuring effective management and compliance. The grantee institution has information on the full extent of investigators' research endeavors and the authority and responsibility to direct investigators' activities. NIH is, in a similar manner, responsible for its employees and has the authority and responsibility to monitor and enforce regulatory requirements pertaining to them. We believe that the current regulation, in conjunction with our enhanced outreach and oversight efforts, forms an appropriate framework for the effective management of investigator FCOI issues.

3. **Require Institutes to forward to OER all financial conflict of interest reports that they receive from grantee institutions and ensure that OER's conflict of interest database contains information on all conflict of interest reports provided by grantee institutions.**

NIH concurs with this recommendation. We have developed a new Web-based FCOI Reporting System for NIH staff. The NIH-wide system will track FCOI notifications received by each Institute or Center (IC) and will assist ICs in reviewing and managing them. The NIH FCOI Reporting System will be fully functional and available for use by the end of 2007; we anticipate that use of the System will be mandatory by March 1, 2008.

OIG Findings:

NIH could not provide an accurate count of the financial conflict of interest reports that it received from grantees during fiscal years 2004 through 2006.

The OIG's observation is correct. NIH ICs are responsible for managing FCOI notifications and are therefore the official receipt point for FCOI notifications. Most ICs maintain FCOI notifications with individual grant files because the notifications are grant-specific and investigator-specific and are considered by IC officials on a case-by-case basis. This has proven to be an effective way for ICs to implement the regulation, but it is problematic when asked to produce all reports for a specific time period. We recognize that NIH needs a way to account for FCOI notifications accurately, and we have developed a new Web-based NIH FCOI Reporting System for NIH staff. The NIH-wide system will track FCOI notifications received by each IC and will assist ICs in reviewing and managing them. As an adjunct to this system, NIH is developing an FCOI module in the eRA Commons that will permit grantee institutions to report identified FCOIs electronically. The internal Web-based system has been designed so that it will interface with the eRA Commons module to provide NIH with a full spectrum of tracking and oversight for FCOI notifications.

NIH is not aware of what types of financial conflicts of interest exist within grantee institutions because most financial conflict of interest reports do not state the nature of the conflict since these details are not required to be reported.

Many Institutes' primary method of oversight is reliance on grantee institutions' assurances that financial conflict of interest regulations are followed.

The observation is correct. It is not NIH practice to request details of the nature of the conflicts reported. The regulation specifically states: "...the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced, or eliminated...." The regulation also states: "The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated...." It is NIH practice to require that the Institution certify in grant applications that it will comply with the requirements of the regulation instead of asking for details of how an Institution has managed, reduced, or eliminated FCOIs. This certification provides the basis for a binding agreement between NIH and its grantees, requiring compliance with all of the terms and conditions of award, including the provisions of the FCOI regulation. If a grantee does not comply, NIH may take any necessary and appropriate actions, including administrative or other available remedies.

The majority of the Institutes do not have any proactive methods to ensure that grantees have financial conflict of interest policies.

The observation is correct. The NIH Office of Extramural Research (OER) executes its robust education and outreach program to proactively educate grant recipients on FCOI (among other issues) on behalf of all NIH ICs. Similarly, OER conducts FCOI compliance activities on behalf of the entire NIH.

Institutes infrequently and inconsistently follow up on reported financial conflicts of interest.

The observation is correct. ICs follow up on reported financial conflicts of interest on a case-by-case basis; therefore, no pattern or frequency would be expected.

12/7/07



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Tanaz Dutia served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to this report include Diane Epstein and Maria Johnson, and central office staff who contributed include Ayana Everett.